Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Study of effectiveness and non effectiveness of abdominal massage and non-nutritive sucking on clinical outcomes in preterm infants

Protocol summary

Summary

This study will be done with aim to assessing the effectiveness of abdominal massage and non-nutritive sucking on clinical outcomes in preterm infants. This study is a single blind clinical trial. Study population will be included all of premature infants admitted to the NICU of Imam Reza Hospital in Kermanshah. 42 patients will selected in available method and considering the number of hospitalized cases and numbers table, randomly will placed in two Intervention groups and one control group. In the intervention group, after the hand was warm and soaked in olive oil over a period of 5 days and 2 times every day at 9 am and 21 pm for 15 minutes massage will performed before feeding. During the massage supine position with the angle of 30-45 degrees head of bed are respected and according to the Vaymala techniques, abdominal massage in(I LoveYou) method will be done. second intervention group will receive non-nutritive sucking by pacifier during the 5 days and 2 times a day at 9 am and 21 pm, that 5 minutes before feeding begins and continues for 10 minutes. The control group will receive routine care. In all three groups, respiratory rate, heart rate and oxygen saturation percentage by Pulse Oximetery pre- and post-intervention, gastric residual volume and frequency of stools will be recorded. Inclusion criteria: No intestinal obstruction and abdominal. Surgery exclusion criteria: Hemodynamic instability, sepsis, severe congenital malformation

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201410275168N9**
Registration date: **2016-06-18, 1395/03/29**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-06-18, 1395/03/29

Registrant information

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Maliheh Assadollahi
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-06-14, 1395/03/25

Expected recruitment end date

2016-08-15, 1395/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of effectiveness and non effectiveness of abdominal massage and non-nutritive sucking on clinical outcomes in preterm infants

Public title

Study the effectiveness of abdominal massage and non-nutritive sucking on clinical outcomes in preterm infants

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Parental consent; Infants with gestational age between (32-28); Weighing between 1750-1000 g; No bowel obstruction and abdominal surgery .Exclusion criteria: The central nervous system Diseases; Severe congenital abnormalities such as severe heart abnormalities and abdominal and intestinal disorders; Sepsis; Hemodynamic instability; Parents opting out of participation in the study; Catching necrotizing enterocolitis; A congenital anomaly abdomen and abdominal surgery; Wound and oral anomalies.
Age
From **7 months** old to **8 months** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomly based on random numbers table

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Vice Chancellor for Research, Tabriz University of Medical Sciences, Street of Golgasht
City
Tabriz
Postal code
Approval date
2016-05-23, 1395/03/03
Ethics committee reference number
IR.TBZMED.REC.1395.158

Health conditions studied

1

Description of health condition studied
preterm infant
ICD-10 code
P07.3
ICD-10 code description
Other preterm infants

Primary outcomes

1

Description
Respiratory rate
Timepoint
The beginning of the study, the first day of initiation of breast feeding twice a day over five days
Method of measurement
Counting the abdominal breathing by facilitator

2

Description
Heart rate
Timepoint
The beginning of the study, the first day of initiation of breast feeding twice a day over five days
Method of measurement
By Pulse Oximetry

3

Description
Oxygen saturation percentage
Timepoint
The beginning of the study, the first day of initiation of breast feeding twice a day over five days
Method of measurement
By Pulse Oximetry

4

Description
Gastric residual volume
Timepoint
The beginning of the study, the first day of initiation of breast feeding twice a day over five days
Method of measurement
By aspiration with syringe

5

Description
The frequency of stools
Timepoint
Baseline, every day for five days
Method of measurement
Observe by facilitator

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, after the hand was warm and soaked in olive oil over a period of 5 days and 2 times every day at 9 am and 21 pm for 15 minutes massage will performed before feeding. During the massage supine position with the angle of 30-45 degrees head of bed are respected and according to the Vaymala techniques, abdominal massage in(I LoveYou) method will be done.
Category
Behavior

2

Description
ẻcond intervention group will receive non-nutritive sucking by pacifier during the 5 days and 2 times a day at 9 am and 21 pm, that 5 minutes before feeding begins and continues for 10 minutes and in total will take 15 minutes.
Category
Behavior

3

Description
The control group will receive routine care.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Sharareh Kiani
Street address
Emam Reza Hospital, Parastar Boulevard
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mehdi Farhoudi
Street address
Vice Chancellor for Research, Tabriz University of Medical Sciences, Street of Golgasht
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Sharareh Kiani
Position
Student of Ms, Emergency care of infant
Other areas of specialty/work
Street address
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mallihe Assadollahi
Position
Ms.c of Nursing
Other areas of specialty/work
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School of Nursing & Midwifery, Tabriz University of Medical Sciences, Shariati Avenue South
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Person responsible for updating data

Contact

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Student of Ms. Nursing of Emergency care of infant

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty